Submitting Archival Files

To the CDER

Electronic Document Room

Electronic
Document
Room

Greg Warzala

Director, Division of Data Management & Services

September 25, 1997

Submitting Archive Files

Electronic
Document
Room

- ***The Guidance has been written to make all our lives easier . . .***

Submitting Archive Files

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- ## *We Want to Outline*

  – *Sponsors' Part*

  – *Our Part*

To make things go smoothly

Submitting Archive Files The Sponsor's Part . . .

Electronic Document Room

- ## **Preparing the materials** -
  - *– file organization &*
  - *– file names are*

  Critical to a successful mount

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The Sponsor's Part . . .

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- ## Acceptable Media
  - ### 3.5 inch diskettes (10)
  - ### ISO 9660 CD-ROMs (5)
  - ### DLT 20/40 or 10/20 GB tape
    Backups created using
    OPENVMS or Windows NT

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- ## **_All Electronic Submissions_**

  (Including Amendments & Supplements)

  ## Send to:

  CDER Central Document Room

  12229 Wilkins Ave.

  Rockville, Md. 20852

Submitting Archive Files
The EDR Staff Will . . .

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- **Complete Standard Processing**
  - –Bar Code and Scan
  - –Separate Electronic & Paper
  - –Move to the EDR

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The EDR Staff Will . . .

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- **_Begin Electronic Processing_**
    - *Initial Inspection*
    - *Upload to VMS Server*

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- **Check for Conformance**
  - *Information Presentation*
  - *Links & Navigation*
  - *Indexing*

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- ## **Create Archival Tapes**
  - *Transfer to Appropriate Network Location*
  - *Enter Location into Database*
  - *Notify SCSO, CSO, Division Document Rooms*

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The EDR Staff Will . . .

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- ## *Two Archival Tapes*
  - ### *One Stored at CDR*
  - ### *One Copied to Network and Incorporated into Backup Routines*

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- **Problem Resolution** -
  - *Complete logs & technical data*
  - *Recommendations*

  SCSO will contact sponsors

Submitting Archive Files

Archival Electronic Submission From Sponsor

Reviewers' Workstations

Desktop System

Desktop System

Building Local Server

Data

Tape

Workgroup Alpha Server

FDDI Ring

Central Document Room

CD-ROM

DAT Tape

EDR Workstation

COMIS Workstations

DLT Tape

Router

EDR NT Server

VMS Server

T1 Line

Tape

"Sneaker Net"

Router

System Console

Disk array

Tape

Alpha Cluster

Parklawn Server Room